

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Dec 2021

Evaluating the efficacy and safety of intravenous immunoglobulin (IVIG) in COVID-19 patients

Protocol summary

Study aim

Determination of the efficacy and safety of IVIG in treatment of patients with COVID-19

Design

Prospective clinical trial with parallel randomized groups

Settings and conduct

Place of study: Masih Daneshvari Hospital. How to do the study: 80 patients with COVID-19 will be randomly divided in to intervention and control group.

Participants/Inclusion and exclusion criteria

Patients who are diagnosed with COVID-19 by RT-PCR test, who are severely ill, and are between 18 to 65 years old. Patients with oxygen saturation <90% (at rest with nasal cannula 3-4 L/min and FIO₂<30-40 L/min) with bilateral pulmonary infiltration were included in the study. Furthermore, patients with allergic reaction while injecting IVIG with severe extravasation and anaphylactic shock, and mildly ill patients were excluded from the study.

Intervention groups

Patients in treatment group will receive hydroxychloroquine 200 mg (Tehran Daroo) twice daily + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days + IVIG (Biotest) 400 mg/Kg for 3 doses. patients in control group will only receive hydroxychloroquine 200 mg (Tehran Daroo) twice daily + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days.

Main outcome variables

Need for mechanical ventilation, need of admission to critical care unit, and death.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N20**

Registration date: **2020-07-26, 1399/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-26, 1399/05/05**

Update count: **0**

Registration date

2020-07-26, 1399/05/05

Registrant information

Name

Farzaneh Dastan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 270 5933

Email address

f_dastan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-09, 1399/04/19

Expected recruitment end date

2020-08-09, 1399/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy and safety of intravenous immunoglobulin (IVIG) in COVID-19 patients

Public title

Evaluating the effects of intravenous immunoglobulin (IVIG) in COVID-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between 18 and 65 years old. Laboratory confirmed COVID-19 (Corona Virus Disease-19) with RT-PCR (Real-Time Polymerase Chain Reaction). Severely ill patients. Bilateral pulmonary infiltration. SPO2 (Peripheral Capillary Oxygen Saturation) less than 90% (at rest with nasal cannula 3-4 L/min and FIO2 less than 30-40 L/min). Signed consent form.

Exclusion criteria:

Allergy reaction while injecting IVIG with severe extravasation and anaphylactic shock. Mildly ill patient. Pregnancy or breast feeding.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method was used in this study. Eight blocks including 10 patients generated with online website. In each block, five patients will be assigned to IVIG group and five patients will be assigned to control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2020-07-07, 1399/04/17

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.143

Health conditions studied

1

Description of health condition studied

COVID-19 pneumonia

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Need for mechanical ventilation

Timepoint

Daily until discharge

Method of measurement

Medical record

2

Description

Need of admission to critical care unit

Timepoint

Daily until discharge

Method of measurement

Medical record

3

Description

Death

Timepoint

From first day of admission until 28 days

Method of measurement

Medical record

Secondary outcomes

1

Description

Severity of symptoms

Timepoint

First day of study then 7 and 14 days after the beginning of the study

Method of measurement

Medical record

2

Description

Lung radiology changes

Timepoint

At admission time and 7 and 14 days later

Method of measurement

Computed tomography

Intervention groups

1

Description

Intervention group: Patients in treatment group will receive hydroxychloroquine 200 mg (Tehran Daroo) twice daily + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days + IVIG (Biotest) 400 mg/Kg for 3 doses.

Category

Treatment - Drugs

2

Description

Control group: patients will only receive hydroxychloroquine 200 mg (Tehran Daroo) twice daily + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Payam Tabarsi

Street address

Masih Daneshvari Hospital, Shahid Bahonar Street (Niyavaran), Darabad.

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2712 3000

Email

payamtabarsi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

3rd floor, School of Medicine, Evin St, Shahid

Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 23871

Email

mpd@sbm.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Payam Tabarsi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Infectious diseases

Street address

Shahid Bahonar St., Darabad St

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2610 5050

Email

payamtabarsi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farzaneh Dastan

Position

Assistant Professor, Clinical Pharmacy Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Shahid Beheshti University of
Medical Sciences, Intersection of Niyayesh Highway,
Valieasr St.

City

Tehran

Province

Tehran

Postal code

1991953381

Phone

+98 21 8820 0118

Email

f_dastan@sbm.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Mirshafiei Langari

Position

Hospital pharmacist

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

City

Tehran

Province

Tehran

Postal code

19569-44413

Phone

+98 21 2712 2066

Email

z.mirshafei@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

All potential data can be shared after blinding

When the data will become available and for how long

Six months after publishing the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For research purposes and meta-analysis studies

From where data/document is obtainable

Dr. farzaneh Dastan, Dr. Masih Daneshvari Hospital,
Daar-Abad, Niavaran

What processes are involved for a request to access data/document

Official letter to the researchers

Comments